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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,236	01/04/2005	Shogo Miki	81844-0032	5109

26021 7590 02/10/2006

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EXAMINER	
THANH, LOAN H	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/520,236	MIKI ET AL.	
	Examiner	Art Unit	
	LoAn H. Thanh	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/04/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 01/04/05 was filed before the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zadno-Azizi et al. (USPN 5,833,644) in view of Keown (USPN 5,667,521).

Zadno-Azizi et al. disclose an aspiration catheter comprising a main shaft 282, a guidewire shaft with a guidewire lumen 286, and a hub at the proximal end of the shaft 282 wherein the tip of the main shaft is obliquely cut and the guidewire shaft is positioned at the distal end of the main shaft. Zadno-Azizi et al. show the L2 /L1 greater than or equal to 0.5 and discloses that the guidewire lumen can be as short as 5cm (50mm) or as long as 30cm or longer. However L2-L1 is not <= 5 mm. Keown discloses a rapid exchange catheter with a variety of different lengths for the guidewire lumen. Specifically , Keown shows the different guidewire lengths in figures 9A to 9E.

Keown teaches that a short guidewire lumen results in less friction and a faster exchange, pinching of the guidewire is minimized as the catheter is being removed through the tortuous path thereby tending to minimize pulling out the guidewire upon withdrawal of the catheter. It would have been obvious to one of ordinary skill in the guidewire art to modify the length of the guidewire shaft of Zadno-Azizi et al. as taught by Keown in order to provide less friction, faster exchange , minimized pinching of guidewire through the tortuous pathway. Further, optimization within prior art conditions through routine experimentation is well known. Generally, differences in lengths will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such length is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

With respect to claim to 2, it would have been an obvious choice of design through routine experimentation to modify the length of the tip of the bevel as claimed in order to provide an optimal length as desired for use in the intended target area.

With respect to claims 3 and 4, Zadno-Azizi et al. does not disclose a radiopaque marker in the guidewire shaft. Keown discloses a radiopaque marker on the catheter in order to visualize where distal portion of the catheter is by fluoroscopy. It would have been obvious to one of ordinary skill in the art at the time the invention was made to put a radiopaque marker on the guidewire shaft (specifically on the distal portion on the catheter) as taught by Keown in order to provide a means for

visualization the location or guiding of the distal portion of the catheter under fluoroscopy.

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zadno-Azizi et al. (USPN 5,833,644) in view of Keown (USPN 5,667,521) and further in view of Sepetka et al. (USPN 5,308,342).

Zadno-Azizi et al. in view of Keown discloses the invention as substantially claimed. However, Zadno-Azizi et al. in view of Keown is silent to the flexural modulus of 1GPa or more. Sepetka et al. discloses a catheter comprising a proximal portion with a flexural modulus of 1.5 or 1.8 Gpa to provide the stiffest portion at the proximal portion in order to provide for to provide for better control and trackability and flexibility when traversing the tortuous pathways. It would have been obvious to one of ordinary skill in the catheter art to modify the main shaft of the Zadno-Azizi et al. in view of Keown with a flexural modulus of greater than 1Gpa in as taught by Sepetka in order to provide for better control, flexibility and less kinking of the catheter traversing the tortuous pathways within the patient.

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zadno-Azizi et al. (USPN 5,833,644) in view of Keown (USPN 5,667,521) in view of (Weaver et al. (USPN 5,536,248).

Zadno-Azizi et al. in view of Keown discloses the invention as substantially claimed. However, Zadno-Azizi et al. in view of Keown is silent to a hydrophilic coating at least on the distal portion of the main shaft. Weaver et al. disclose a hydrophilic

coating on the distal portion of the catheter which serves the function of softening the catheter body so as to increase its suppleness and kink resistance and lubricity. Further, the softened distal portion is less traumatic to the tissue within the body passage. It would have been obvious to one of ordinary skill in the catheter art at the time the invention was made to modify the distal portion of catheter of Zadno-Azizi et al. in view of Keown with a hydrophilic coating as taught by Weaver et al. in order to provide a lubricious catheter to traverse the tortuous pathways with link resistance.

Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zadno-Azizi et al. (USPN 5,833,644) in view of Keown (USPN 5,667,521) and further in view of Sepetka et al. (USPN 5,308,342).

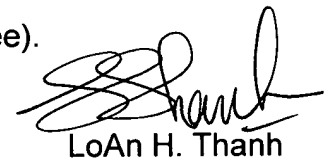
Zadno-Azizi et al. in view of Keown and further in view of Sepetka et al. disclose the invention as substantially claimed. However Zadno-Azizi et al. in view of Keown and further in view of Sepetka et al. is silent to a hydrophilic coating at least on the distal portion of the main shaft. Weaver et al. disclose a hydrophilic coating on the distal portion of the catheter which serves the function of softening the catheter body so as to increase its suppleness and kink resistance and lubricity. Further, the softened distal portion is less traumatic to the tissue within the body passage. It would have been obvious to one of ordinary skill in the catheter art at the time the invention was made to modify the distal portion of catheter of Zadno-Azizi et al. in view of Keown and further in view of Sepetka et al. with a hydrophilic coating as taught by Weaver et al. in order to provide a lubricious catheter to traverse the tortuous pathways with link resistance.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LoAn H. Thanh
Primary Examiner
Art Unit 3763

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